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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/671,817	09/27/2000	Aled Edwards	11670/2	5923

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EXAMINER

BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 07/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/671,817

Applicant(s)

Edwards et al

Examiner

Michael Borin

Art Unit

1631



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.

- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.

- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.

- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Apr 7, 2003

2a) ☐ This action is FINAL.

2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-71 is/are pending in the application.

4a) Of the above, claim(s) 4, 6-37, 44-57, 65, and 66 is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-3, 5, 38-43, 58-64, and 67-71 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims 1-3, 5, 38-43, 58-64, and 67-71 are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

4) ☐ Interview Summary (PTO-413) Paper No(s). _____

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

5) ☐ Notice of Informal Patent Application (PTO-152)

3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

6) ☐ Other:

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DETAILED ACTION

Examiner of record has changed. Please forward all correspondence to Examiner Michael Borin, AU 1631.

Status of Claims

Claims 67-71 are added. Claims 1-71 are pending. Claims 4,6-37,44-57,65,66 are withdrawn from consideration. Claims 1-3,5,38-43,58-64, 67-71 are under consideration. Claims 1,3,58 are amended.

Upon review of the application it was deemed necessary, before addressing the issues of record, to apply an additional restriction requirement, and a rejection under 35 U.S.C. 112, second paragraph which applies equally to any of the groups recited in the following restriction requirement. The issues of record will be addressed upon selection of an invention and response to rejection under 35 U.S.C. 112, second paragraph.

Further restriction

Upon further consideration of the restriction requirement made in this application, the following additional restriction of Group I was deemed necessary.

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Restriction to one of the following inventions is required under 35 U.S.C. 121:

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- IA. Claims 1-3,5,38-43, 67-69 drawn to method of determining biochemical/biophysical properties of a protein, drawn to class 702, subclass 20.
- IB. Claims 58-64,70,71, drawn to method of optimizing protein expression, drawn to class 435, subclass 69.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions IA and IB are independent and/or patentably distinct because the methods have different functions and different effects (determining properties of a protein vs. optimizing protein expression) and have different modes of operation (invention IA does not require step of protein expression). A reference teaching determining protein properties will not teach or suggest optimizing expression of this protein; *vice versa*, a reference teaching optimizing protein expression will not teach or suggest determining protein properties.

Because these inventions are distinct for the reasons given and have acquired a separate status in the art as shown by their different classification, and because of

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their recognized divergent subject matter, and the necessity for non-coextensive literature searches restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Claim Rejections - 35 USC § 112, second paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3,5,38-43, 58-64,67-71 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The stated objective of method of claim 1 is determination of properties of a protein. However, step a) of claim 1 already assumes that, for a given protein, this properties of a protein are already provided in a database. Hence, the question is, what remains to be determined?

Further, method steps whereby a sequence is analyzed using correlation to biophysical/biochemical properties are not clear. For example, how knowledge of

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amide hydrogen exchange, or conditions of crystallization, or behavior during mass spectrometry, is applied to analyzing protein sequence (wherein the latter is predetermined sequence of connected amino acid residues in a protein). Such knowledge does not seem to be helpful in clarifying sequence of connected amino acid residues in a protein. And again, how is analyzing sequence using known functional properties of a protein will assist in determining same functional properties which are already known.

The same applies to method steps a)-c) of Group IB.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

June 24, 2003

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

